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I, JONNE YABSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2002953468 for a patent by COCHLEAR LIMITED as filed on 19 December 2002.

WITNESS my hand this
Ninth day of January 2004

J R Yabsley

JONNE YABSLEY
TEAM LEADER EXAMINATION
SUPPORT AND SALES

AUSTRALIA

Patents Act 1990

Cochlear Limited

PROVISIONAL SPECIFICATION

Invention Title:

A method of sealing a lumen in an electrode assembly

The invention is described in the following statement:

Field of the Invention

The present invention relates to an implantable device and, in particular, to an implantable cochlear electrode assembly.

Background of the Invention

Hearing loss, which may be due to many different causes, is generally of two types, conductive and sensorineural. Of these types, conductive hearing loss occurs where the normal mechanical pathways for sound to reach the hair cells in the cochlea are impeded, for example, by damage to the ossicles.. Conductive hearing loss may often be helped by use of conventional hearing aid systems, which amplify sound so that acoustic information does reach the cochlea and the hair cells.

In many people who are profoundly deaf, however, the reason for deafness is sensorineural hearing loss. This type of hearing loss is due to the absence of, or destruction of, the hair cells in the cochlea which transduce acoustic signals into nerve impulses. These people are thus unable to derive suitable benefit from conventional hearing aid systems, because there is damage to or absence of the mechanism for nerve impulses to be generated from sound in the normal manner.

It is for this purpose that cochlear implant systems have been developed. Such systems bypass the hair cells in the cochlea and directly deliver electrical stimulation to the auditory nerve fibres, thereby allowing the brain to perceive a hearing sensation resembling the natural hearing sensation normally delivered to the auditory nerve. US Patent 4532930, the contents of which are incorporated herein by reference, provides a description of one type of traditional cochlear implant system.

Cochlear implant systems have typically consisted of two key components, namely an external component commonly referred to as a processor unit, and an implanted internal component commonly referred to as a receiver/stimulator unit. Traditionally, both of these components have cooperated together to provide the sound sensation to an implantee.

The external component has traditionally consisted of a microphone for detecting sounds, such as speech and environmental sounds, a speech processor that

converts the detected sounds and particularly speech into a coded signal, a power source such as a battery, and an external antenna transmitter coil.

The coded signal output by the speech processor is transmitted transcutaneously to the implanted receiver/stimulator unit situated within a recess of the temporal bone of the implantee. This transcutaneous transmission occurs through use of an inductive coupling provided between the external antenna transmitter coil which is positioned to communicate with an implanted antenna receiver coil provided with the receiver/stimulator unit. This communication serves two essential purposes, firstly to transcutaneously transmit the coded sound signal and secondly to provide power to the implanted receiver/stimulator unit. Conventionally, this link has been in the form of a radio frequency (RF) link, but other such links have been proposed and implemented with varying degrees of success.

The implanted receiver/stimulator unit typically includes the antenna receiver coil that receives the coded signal and power from the external processor component, and a stimulator that processes the coded signal and outputs a stimulation signal to an intracochlea electrode assembly which applies the electrical stimulation directly to the auditory nerve producing a hearing sensation corresponding to the original detected sound.

The external componentry of the cochlear implant has been traditionally carried on the body of the implantee, such as in a pocket of the implantee's clothing, a belt pouch or in a harness, while the microphone has been mounted on a clip mounted behind the ear or on a clothing lapel of the implantee.

More recently, due in the main to improvements in technology, the physical dimensions of the speech processor have been able to be reduced allowing for the external componentry to be housed in a small unit capable of being worn behind the ear of the implantee. This unit has allowed the microphone, power unit and the speech processor to be housed in a single unit capable of being discretely worn behind the ear, with the external transmitter coil still positioned on the side of the user's head to allow for the transmission of the coded sound signal from the speech processor and power to the implanted stimulator unit.

Together with improvements in available technology, much research has been undertaken in the area of understanding the way sound is naturally processed by the human auditory system. With such an increased understanding of how the cochlea naturally processes sounds of varying frequency and magnitude, there is a need to provide an improved cochlear implant system that delivers electrical stimulation to the auditory nerve in a way that takes into account the natural characteristics of the cochlea.

It is known in the art that the cochlea is tonotopically mapped. In other words, the cochlea can be partitioned into regions, with each region being responsive to signals in a particular frequency range. This property of the cochlea is exploited by providing the electrode assembly with an array of electrodes, each electrode being arranged and constructed to deliver a cochlea stimulating signal within a preselected frequency range to the appropriate cochlea region. The electrical currents and electric fields from each electrode stimulate the cilia disposed on the modiolus of the cochlea. Several electrodes may be active simultaneously.

It has been found that in order for these electrodes to be effective, the magnitude of the currents flowing from these electrodes and the intensity of the corresponding electric fields, are a function of the distance between the electrodes and the modiolus. If this distance is relatively great, the threshold current magnitude must be larger than if the distance is relatively small. Moreover, the current from each electrode may flow in all directions, and the electrical fields corresponding to adjacent electrodes may overlap, thereby causing cross-electrode interference. In order to reduce the threshold stimulation amplitude and to eliminate cross-electrode interference, it is advisable to keep the distance between the electrode array and the modiolus as small as possible. This is best accomplished by providing the electrode array in the shape which generally follows the shape of the modiolus. Also, this way of delivering the electrical stimulation to the auditory nerve is most effective as the electrode contacts are as close as possible to the auditory nerves that are particularly responsive to selected pitches of the sound waves.

In order to achieve this electrode array position close to the inside wall of the cochlea, the electrode needs to be designed in such a way that it assumes this position upon or immediately following insertion into the cochlea. This is a challenge as the array needs to be shaped such that it assumes a curved shape to conform with the shape

of the modiolus and must also be shaped such that the insertion process causes minimal trauma to the sensitive structures of the cochlea. In this sense, it has been found to be desirable for the electrode array to be generally straight during the insertion procedure.

Several procedures have been adopted to provide an electrode assembly that is relatively straightforward to insert while adopting a curved configuration following insertion in the cochlea. In one case, a straight platinum wire stylet is positioned within a lumen extending along at least a portion of the length of the assembly. The stylet is relatively stiffer than the body of the assembly and serves to hold a pre-curved electrode array in a generally straight configuration up until insertion. Following insertion, the platinum stylet is withdrawn from the lumen allowing the array to return to its pre-curved configuration.

The presence of any lumen within the electrode assembly for the stylet may pose a potential pathway for pathogens including harmful bacteria, to migrate from a location external the cochlea into the cochlea if there is an opening from the lumen into the cochlea.. While most implants are typically designed and constructed to ensure there is no potential pathway, other circumstances may dictate that such a lumen or an opening from such a lumen is desirable. In this case, the present invention provides a mechanism for preventing any potential migration of pathogens through the assembly.

While the above description of the prior art is directed to cochlear implant electrode assemblies, similar issues of potential pathogen migration arise in other implantable devices using electrode assemblies, such as midbrain implants and muscle stimulation systems used in function electronic stimulation (FES) systems.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed in Australia before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

According to a first aspect, the present invention is an implantable tissue-stimulating device comprising:

a resiliently flexible elongate member having a proximal end and a distal end and having at least one electrode mounted thereon;

a lumen extending into and along at least a portion of the elongate member from an orifice positioned at or relatively closer to the proximal end than the distal end; and

a compression member mountable around at least a portion of the elongate member;

wherein the compression member is adjustable between a first configuration in which the compression member does not compress a portion of the lumen and a second configuration in which the compression member does compress at least a portion of the lumen.

In one embodiment, the lumen is preferably adapted to receive a stiffening element through the orifice thereof.

The lumen of the elongate member can be the same diameter along at least a majority or all of its length. In another embodiment, the lumen can have a region of lesser diameter at or adjacent the orifice of the lumen. In one embodiment, the compression member can be positioned around the elongate member at the region of lesser diameter. In one embodiment, the position of the compression member around the elongate member can be adjustable. An indicating means can be provided to allow external identification of the location of the region of lesser diameter. Such an indicating means may include a visual indicating means.

In a further embodiment, the compression member is preferably only adjustable once from the first configuration to the second configuration. As such, once the compression member has been adjusted to adopt a second configuration, it preferably remains in that configuration. Adjustment of the configuration is preferably performed by the surgeon during the implantation procedure for the elongate member. Where a stiffening element is positioned in the lumen, the stiffening element is preferably

withdrawn during the implantation procedure. Following withdrawal of the stiffening element, the surgeon or another assisting in the surgical procedure can adjust the crimp and so preferably compress at least a portion of the lumen.

In any embodiment, the compression member can be formed from a biocompatible material. In one embodiment, the compression member can comprise a ring of material. The ring can be formed of metallic material, such as stainless steel, titanium, or a suitable alloy. In another embodiment, the compression member can be formed of a biocompatible plastics materials such as ABS or polypropylene. In these embodiments, the compression member can be in the form of a crimp. The crimp can be compressed flat or in another configuration, such as a zig-zag pattern. A compressing tool shaped to suit the dimensions of the crimp could be utilised in this regard.

In another embodiment, the compression member can comprise a clip which is mountable around the elongate member and which can then be closed and latched. The dimensions of the clip relative to the elongate member are preferably such that on closing and latching of the clip, at least a portion of the lumen is compressed sufficiently to at least substantially seal the lumen. The clip is preferably capable of manipulation by the hands of the surgeon. A suitable tool for performing this function can, however, also be envisaged. Such a clip can be formed from a biocompatible plastics material, such as polypropylene.

According to a second aspect, the present invention is an implantable tissue-stimulating device comprising:

a resiliently flexible elongate member having a proximal end and a distal end and having at least one electrode mounted thereon; and

a lumen extending into and along at least a portion of the elongate member from an orifice positioned at or relatively closer to the proximal end than the distal end, said lumen being adapted to receive a stiffening element through the orifice;

wherein the lumen has a first portion of a first diameter and at least one second portion having a diameter less than that of the first portion;

wherein said second portion is relatively closer to the orifice of the lumen than at least one of said first lumen portions.

The second portion of the lumen can have a diameter that is about the same or less than the diameter of the stiffening element passing therethrough. In one embodiment, the diameter of the second portion can be about 0.1mm. The diameter of the first portion can be about 0.18mm. In yet another embodiment, the second portion can have a length of about 5mm.

In one embodiment, the second portion can be spaced from the orifice of the lumen by at least one first portion.

In a further embodiment, the second portion can be compressed by a compression member as defined herein according to the first aspect of the invention. In another embodiment, the orifice of the lumen can have a quantity of adhesive inserted therein that subsequently cures and seals the lumen. The adhesive can be a cyanoacrylate.

In this aspect, at least the second portion of the lumen can be coated with a material that swells on contact with at least certain fluids. For example, the second portion of the lumen can have a coating of a hydrogel material that swells following contact with body fluids. The hydrogel can have a coating to allow control of the commencement time or rate of swelling of the hydrogel. The swelling of the hydrogel is preferably such that the second portion is sealed following withdrawal of the stiffening element.

According to a third aspect, the present invention is an implantable tissue-stimulating device comprising:

a resiliently flexible elongate member having a proximal end and a distal end and having at least one electrode mounted thereon; and

a lumen extending into and along at least a portion of the elongate member from an orifice positioned at or relatively closer to the proximal end than the distal end, said lumen being adapted to receive a stiffening element through the orifice;

wherein at least a portion of the lumen is coated with a layer of material that swells following exposure to bodily fluids.

According to a fourth aspect, the present invention is an implantable tissue-stimulating device comprising:

a resiliently flexible elongate member having a proximal end and a distal end and having at least one electrode mounted thereon; and

a lumen extending into and along at least a portion of the elongate member from an orifice positioned at or relatively closer to the proximal end than the distal end, said lumen being adapted to receive a stiffening element through the orifice;

wherein the lumen in the region adjacent the orifice decreases in diameter away from the orifice into the elongate member for a length.

In this aspect, said region of the lumen is preferably frusto-conical in form. The shape and dimensions of said region are preferably such that at least part of the region can be packed with fibrous tissue following withdrawal of the stiffening element.

In a preferred embodiment of the aspects, the stiffening element can be formed from a non-bioresorbable material. In this embodiment, the stiffening element can comprise a metallic stylet, or a stylet-like element formed from any other suitable stiffening material, extending through the lumen in the elongate member. In one embodiment, the stylet can be formed from a biocompatible metal, a biocompatible metallic alloy or a biocompatible relatively stiff plastic. In a preferred embodiment, a metal stylet can be formed from platinum.

In a preferred embodiment of this invention, the device is a cochlear implant electrode assembly. In another embodiment, the device is adapted to deliver stimulation to the brain, such as the midbrain. Still further, the device can be adapted to deliver functional electrical stimulation to one or more muscle groups in the body of an implantee.

In a further embodiment, the distal end of the elongate member is adapted to be inserted firstly into the implantee.

The lumen can be cylindrical or have any other suitable cross-sectional shape. In one embodiment, the lumen extends through the elongate member for a substantial portion of its length. In a further embodiment, the lumen extends from an opening at the proximal end of the elongate member to a position that is adjacent the distal end thereof.

In a further embodiment, the elongate member can have a plurality of electrodes mounted thereon. In one embodiment, the electrodes can be formed of a biocompatible metallic material, such as platinum.

In a further embodiment, the elongate member can have a first configuration selected to allow said member to be more readily inserted into an implantee's body, such as the cochlea, and a second configuration wherein said elongate member is more readily adapted to apply a preselected tissue stimulation with the electrodes. In a further embodiment, the elongate member can have at least one intermediate configuration between said first and second configurations.

In a still further embodiment, at least a portion of the outer surface of the elongate member can have a coating of lubricious material. In a further embodiment, a substantial portion of the outer surface can have a coating of the lubricious material. In a still further embodiment, the entire outer surface of the elongate member can have a coating of the lubricious material.

The lubricious material preferably becomes lubricious on being brought into contact with a fluid, such as a saline solution. Still further, the coating preferably becomes lubricious on being brought into contact with a body fluid, such as cochlear fluid.

In one embodiment, the lubricious material is selected from the group comprising polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA). It is envisaged that other similar materials could also be used.

In yet another embodiment, the stiffening element can be made of a second material relatively stiffer than the resiliently flexible material of the elongate member. The stiffening element can be adapted to bias the elongate member into the first configuration.

In a preferred embodiment, the second configuration of the elongate member is curved. More preferably, the elongate member adopts a spiral configuration when in the second configuration.

The elongate member is preferably preformed from a plastics material with memory and is preformed to the second configuration.

In a preferred embodiment, the first configuration is preferably substantially straight. More preferably, the first configuration is straight.

In a preferred embodiment, the elongate member is formed from a suitable biocompatible material. In one embodiment, the material can be a silicone, such as Silastic MDX 4-4210. In another embodiment, the elongate member can be formed from a polyurethane or similar material.

Once implanted, the electrodes can receive stimulation signals from a stimulator device. The stimulator device is preferably electrically connected to the elongate member by way of an electrical lead. The lead can include the one or more wires extending from each electrode of the array mounted on the elongate member.

In one embodiment, the lead can extend from the elongate member to a stimulator device or at least the housing thereof. In one embodiment, the lead is continuous with no electrical connectors, at least external the housing of the stimulator device, required to connect the wires extending from the electrodes to the stimulator device. One advantage of this arrangement is that there is no requirement for the surgeon implanting the device to make the necessary electrical connection between the wires extending from the electrodes and the stimulator device.

The stimulator device is preferably positioned within a housing that is implantable within the implantee. The housing for the stimulator device is preferably implantable within the bony well in the bone behind the ear posterior to the mastoid.

When implantable, the housing preferably contains, in addition to the stimulator device, a receiver device. The receiver device is preferably adapted to receive signals from a controller means. The controller means is, in use, preferably mounted external to the body of the implantee such that the signals are transmitted transcutaneously through the implantee.

Signals can preferably travel from the controller means to the receiver device and vice versa. The receiver device can include a receiver coil adapted to receive radio

frequency (RF) signals from a corresponding transmitter coil worn externally of the body. The radio frequency signals can comprise frequency modulated (FM) signals. While described as a receiver coil, the receiver coil can preferably transmit signals to the transmitter coil which receives the signals.

The transmitter coil is preferably held in position adjacent the implanted location of the receiver coil by way of respective attractive magnets mounted centrally in, or at some other position relative to, the coils.

The external controller can comprise a speech processor adapted to receive signals output by a microphone. During use, the microphone is preferably worn on the pinna of the implantee, however, other suitable locations can be envisaged, such as a lapel of the implantee's clothing. The speech processor encodes the sound detected by the microphone into a sequence of electrical stimuli following given algorithms, such as algorithms already developed for cochlear implant systems. The encoded sequence is transferred to the implanted receiver/stimulator device using the transmitter and receiver coils. The implanted receiver/stimulator device demodulates the FM signals and allocates the electrical pulses to the appropriate attached electrode by an algorithm which is consistent with the chosen speech coding strategy.

The external controller further comprises a power supply. The power supply can comprise one or more rechargeable batteries. The transmitter and receiver coils are used to provide power via transcutaneous induction to the implanted receiver/stimulator device and the electrode array.

While the implant system can rely on external componentry, in another embodiment, the controller means, including the microphone, speech processor and power supply can also be implantable. In this embodiment, the controller means can be contained within a hermetically sealed housing or the housing used for the stimulator device.

Brief Description of the Drawings

By way of example only, a preferred embodiment of the invention is now described with reference to the accompanying drawings, in which:

Fig. 1 is a pictorial representation of a prior art cochlear implant system;

Figs. 2 and 3 are diagrammatic views of a portion of an elongate member having one embodiment of a compression crimp according to the present invention mounted thereto;

Figs. 4 and 5 depict the crimp of Figs 2 and 3 following different types of crimping;

Figs. 6a and 6b depict one embodiment of a compression clip according to the present invention mounted thereto in an open and closed position, respectively;

Fig. 7 is a fragmentary view of an elongate member having a lumen having a narrow region; and

Fig. 8 is a fragmentary view of a further embodiment of an elongate member according to the present invention.

Preferred Mode of Carrying out the Invention

Before describing the features of the present invention, it is appropriate to briefly describe the construction of a typical cochlear implant system with reference to Fig. 1.

Cochlear implants typically consist of two main components, an external component including a speech processor 29, and an internal component including an implanted receiver and stimulator unit 22. The external component includes a microphone 27. The speech processor 29 is, in this illustration, constructed and arranged so that it can fit behind the outer ear 11. Alternative versions may be worn on the body. Attached to the speech processor 29 is a transmitter coil 24 which transmits electrical signals to the implanted unit 22 via a radio frequency (RF) link.

The internal component includes a receiver coil 23 for receiving power and data from the transmitter coil 24. A cable 21 extends from the implanted receiver and stimulator unit 22 to the cochlea 12 and terminates in an electrode array 20. The signals thus received are applied by the array 20 to the basilar membrane 8 and the

nerve cells within the cochlea 12 thereby stimulating the auditory nerve 9. The operation of such a device is described, for example, in US Patent No. 4532930.

While directed to cochlear implants, it will be appreciated that the present invention can apply equally to other tissue-stimulating devices, such as devices adapted to deliver electrical stimulation to the brain or muscles of an implantee.

One embodiment of a compression member for use in sealing the lumen 41 of an elongate member 40 is depicted generally as 30 in Figs. 2 and 3. It will be understood that the elongate member 40 can have a plurality of electrodes mounted thereon.

The compression member 30 comprises a ring that is mountable around at least a portion of the elongate member 40. The member 30 is adjustable between a first configuration (as depicted in Fig. 3) in which the compression member does not compress a portion of the lumen 41 and a second configuration (as depicted, for example, in Figs. 4 and 5) in which the compression member does compress at least a portion of the lumen.

The compression member 30 can be provided on the elongate member at a location where the lumen 41 of the elongate member has a region 42 of lesser diameter as depicted in Fig. 7. An indicating means can be provided to allow external identification of the location of the region 42 of lesser diameter. Such an indicating means may include a visual indicating means.

In the depicted embodiment, the compression member 30 is only adjustable once from the first configuration to the second configuration. As such, once the compression member has been adjusted to adopt a second configuration (as depicted in Figs. 4 and 5), it preferably remains in that configuration. Adjustment of the configuration is preferably performed by the surgeon during the implantation procedure for the elongate member. Where a stiffening element is positioned in the lumen, the stiffening element is preferably withdrawn during the implantation procedure. Following withdrawal of the stiffening element, the surgeon or another assisting in the surgical procedure can adjust the crimp and so preferably compress at least a portion of the lumen.

In the depicted embodiments, the compression member 30 is formed from a biocompatible material. The ring can be formed of metallic material, such as stainless steel, titanium, or a suitable alloy. In another embodiment, the compression member can be formed of a biocompatible plastics materials such as ABS or polypropylene. The ring can be compressed in a manner such that its has a flat portion (as depicted in Fig. 5) or in another configuration, such as a zig-zag pattern as is depicted in Fig. 4. A compressing tool shaped to suit the dimensions of the crimp could be utilised in this regard.

As depicted in Figs. 6a and 6b, the compression member can comprise a clip 50 which is mountable around the elongate member 40 and which can then be closed and latched as depicted in Fig. 6b. The dimensions of the clip relative to the elongate member are preferably such that on closing and latching of the clip, at least a portion of the lumen 41 is compressed sufficiently to at least substantially seal the lumen. The clip 50 is preferably capable of manipulation by the hands of the surgeon. A suitable tool for performing this function can, however, also be envisaged. Such a clip can be formed from a biocompatible plastics material, such as polypropylene.

While the region 42 of the lumen of lesser diameter depicted in Fig. 7 can be used in conjunction with the compression member 30 or the clip 50, the resiliently flexible elongate member can rely on this region to provide at least a partial barrier to transfer of pathogens through the lumen.

In the embodiment depicted in Fig. 7, the region 42 is relatively closer to the orifice 43 of the lumen 41 than at least one of said first lumen portions 41a.

The region 42 has a diameter that is about the same or less than the diameter of the stiffening element passing therethrough. In one embodiment, the diameter of the region 42 can be about 0.1mm. The diameter of the portion 41a can be about 0.18mm. In yet another embodiment, the region 42 can have a length of about 5mm.

As depicted, the region 42 can be spaced from the orifice 43 of the lumen by at least one lumen portion 41b having a diameter greater than that of the region 42.

In this embodiment, the orifice 43 of the lumen can have a quantity of adhesive inserted therein that subsequently cures and seals the lumen. The adhesive can be a cyanoacrylate.

In this embodiment, at least the region 42 can also be coated with a material that swells on contact with at least certain fluids. For example, the region 42 of the lumen can have a coating of a hydrogel material that swells following contact with body fluids. The hydrogel can have a coating to allow control of the commencement time or rate of swelling of the hydrogel. The swelling of the hydrogel is preferably such that the region 42 is sealed following withdrawal of the stiffening element.

Fig. 8 depicts another embodiment of a resiliently flexible elongate member according to the present invention generally as 60. In this embodiment, the elongate member 60 has a lumen 41 extending into and along at least a portion of the elongate member 60 from an orifice 43 positioned at the proximal end. The lumen 41 in a region 41d adjacent the orifice decreases frusto-conically in diameter away from the orifice 43 into the elongate member 60 for a length. The shape and dimensions of the region 41d are such that at least part of the region can be packed with fibrous tissue following withdrawal of the stiffening element.

The stiffening element used in conjunction with the invention can be formed of platinum but it will be appreciated that other biocompatible metals and plastics materials could be employed as a stylet in the present invention. The stylet used in conjunction with the elongate member is relatively stiffer than the silicone elongate member and is adapted to be positioned within the lumen thereof and so straighten the elongate member from its preferentially curved configuration to one that is more readily implantable in the cochlea of an implantee.

The depicted elongate members are preferably preformed from a suitable biocompatible material. In one embodiment, the material can be a silicone, such as Silastic MDX 4-4210. In another embodiment, the elongate member can be formed from a polyurethane or similar material.

Once implanted, the electrodes of the elongate member can receive stimulation signals from a stimulator device. The stimulator device is preferably electrically connected to the elongate member by way of the electrical lead 21.

In one embodiment, the lead can extend from the elongate member to a stimulator device or at least the housing thereof. In one embodiment, the lead is continuous with no electrical connectors, at least external the housing of the stimulator device, required to connect the wires extending from the electrodes to the stimulator device. One advantage of this arrangement is that there is no requirement for the surgeon implanting the device to make the necessary electrical connection between the wires extending from the electrodes and the stimulator device.

The stimulator device is preferably positioned within a housing that is implantable within the implantee. The housing for the stimulator device is preferably implantable within the bony well in the bone behind the ear posterior to the mastoid.

When implantable, the housing preferably contains, in addition to the stimulator device, a receiver device. The receiver device is preferably adapted to receive signals from a controller means. The controller means is, in use, preferably mounted external to the body of the implantee such that the signals are transmitted transcutaneously through the implantee.

Signals can preferably travel from the controller means to the receiver device and vice versa. The receiver device can include a receiver coil adapted to receive radio frequency (RF) signals from a corresponding transmitter coil worn externally of the body. The radio frequency signals can comprise frequency modulated (FM) signals. While described as a receiver coil, the receiver coil can preferably transmit signals to the transmitter coil which receives the signals.

The transmitter coil is preferably held in position adjacent the implanted location of the receiver coil by way of respective attractive magnets mounted centrally in, or at some other position relative to, the coils.

The external controller can comprise a speech processor adapted to receive signals output by a microphone. During use, the microphone is preferably worn on the pinna of the implantee, however, other suitable locations can be envisaged, such as a lapel of the implantee's clothing. The speech processor encodes the sound detected by the microphone into a sequence of electrical stimuli following given algorithms, such as algorithms already developed for cochlear implant systems. The encoded sequence

is transferred to the implanted receiver/stimulator device using the transmitter and receiver coils. The implanted receiver/stimulator device demodulates the FM signals and allocates the electrical pulses to the appropriate attached electrode by an algorithm which is consistent with the chosen speech coding strategy.

The external controller further comprises a power supply. The power supply can comprise one or more rechargeable batteries. The transmitter and receiver coils are used to provide power via transcutaneous induction to the implanted receiver/stimulator device and the electrode array.

While the implant system can rely on external componentry, in another embodiment, the controller means, including the microphone, speech processor and power supply can also be implantable. In this embodiment, the controller means can be contained within a hermetically sealed housing or the housing used for the stimulator device.

The effective delivery of electrode arrays can often be dependent on the use of stylets that are positioned within a lumen of the array. The present invention provides a means of still allowing use of such arrangements while ensuring that the lumen does not subsequently become a pathway for transfer of pathogens through the array and into the implantee.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this nineteenth day of December 2002

Cochlear Limited
Patent Attorneys for the Applicant:

F B RICE & CO

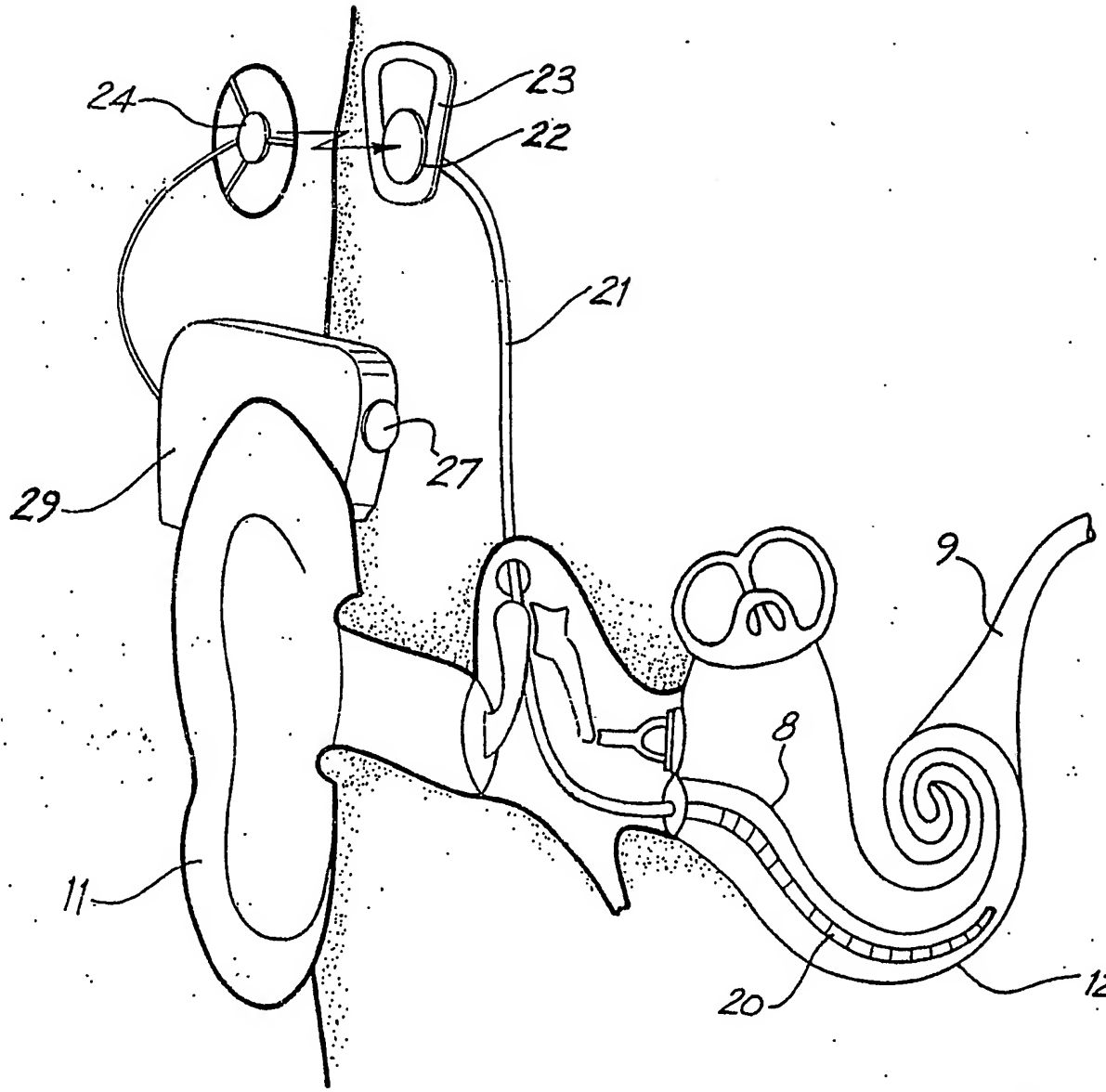

FIG. 1

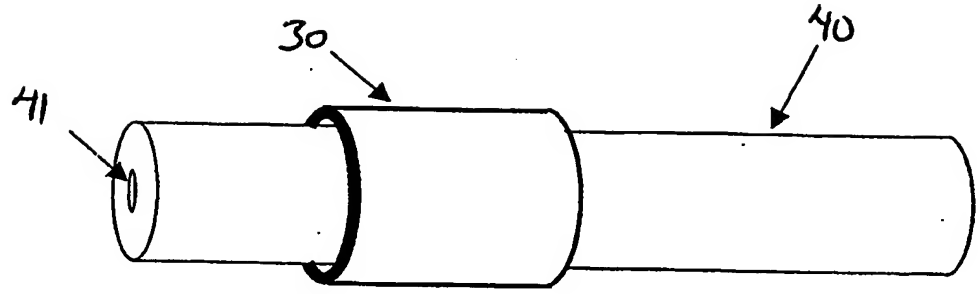

Fig. 2

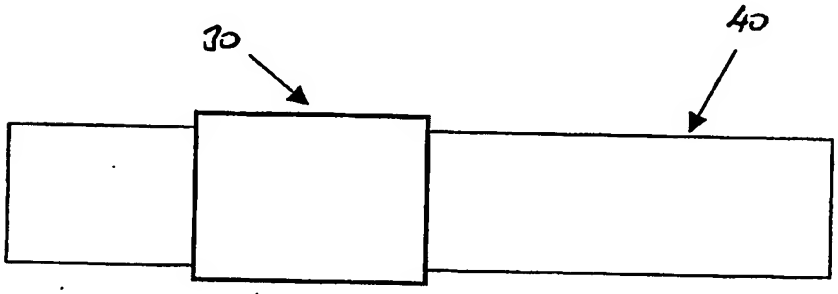

Fig. 3

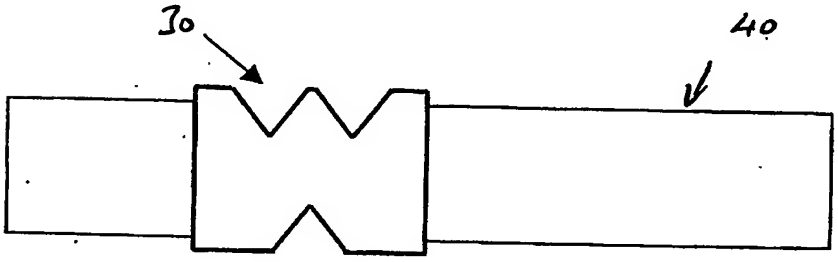

Fig. 4

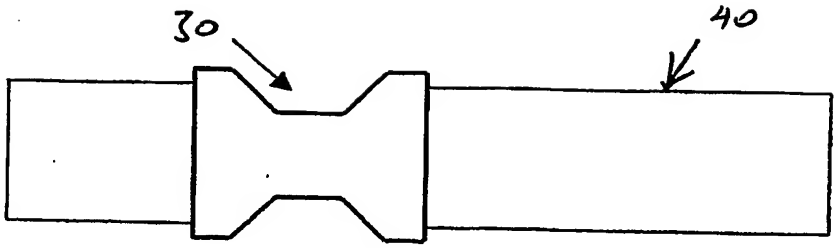

Fig. 5

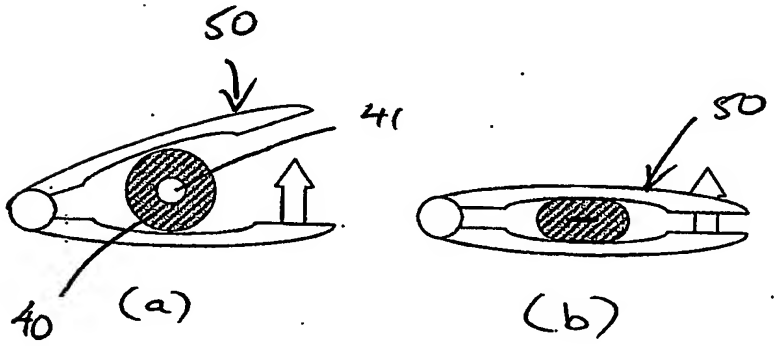

Fig. 6

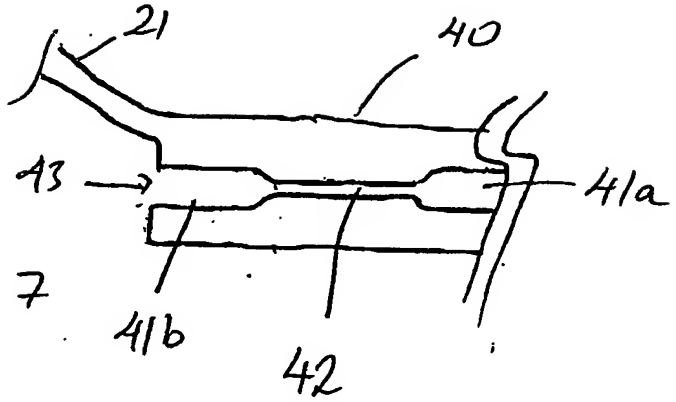

Fig. 7

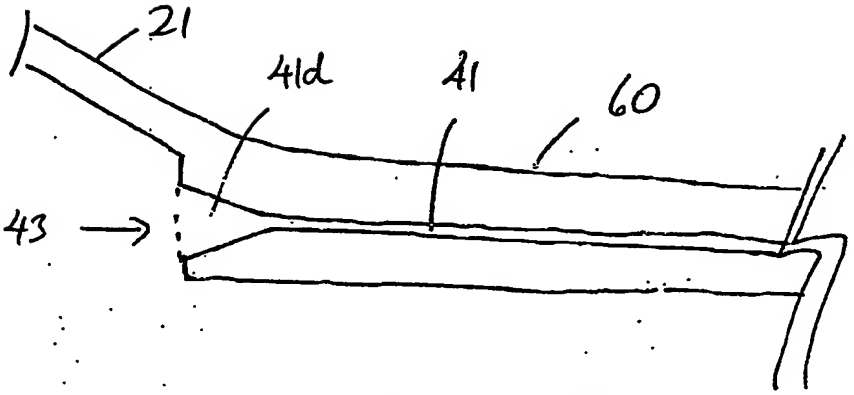

Figure 8

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